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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,568	05/02/2002	Dan L. Eaton	P3230R1C48	9762

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KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
KAPUST, RACHEL B	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,568	EATON ET AL.	
	Examiner	Art Unit	
	Rachel B. Kapust	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0902*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

According to the priority statement of September 10, 2002, the claimed subject matter defined in the instant application is supported by parent application serial nos. 10/006867, PCT/US00/23328, 09/380137, PCT/US99/12252, and 60/089653. Based on the information given by applicant and an inspection of the patent applications, the examiner has concluded that the subject matter defined in this application is not supported by the disclosures of 09/380137, PCT/US99/12252, and 60/089653 because the priority documents are not enabling for the claimed antibody, an anti-PRO 1291 antibody. The current application is a continuation of 10/006867 which is a continuation of PCT/US00/23328 filed August 24, 2000, all of which have the same specification and disclose the same subject matter. Accordingly, the subject matter defined in claims 1-6 has an effective filing date of August 24, 2000.

Should the Applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to August 24, 2000 that specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled prior to August 24, 2000.

Specification

The use of the trademarks KLENTAQ™ (p. 117), QIAQUICK™ (p. 119), SUPERFECT™ (p. 129), FUGENE™ (p. 129), and BACULOGOLD™ (p. 131) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. Claims 1-6 are directed to antibodies that bind to a polypeptide comprising SEQ ID NO: 60. The claimed antibodies are not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The antibodies of the current invention bind to polypeptides comprising SEQ ID NO: 60. However, there is no utility for a polypeptide comprising SEQ ID NO: 60. Uses such as assaying for binding partners (p. 89), using polypeptides as molecular weight markers (p. 92), and screening for agonists and antagonists of PRO 1291 (p. 95) are useful only in research to determine the function of the encoded protein itself. There is no "specific benefit in currently available form" to be derived from such studies. Tissue-specific expression such as that found on p. 142 (see DNA59610-1556) is not specific to the PRO 1291 polypeptide. It does not depend on any characteristics of the polypeptide itself.

Applicants also assert that the antibodies may be modified so that they are effective in the treatment of cancer and HIV infection (p. 108). Applicants further assert the antibodies may be used in pharmaceutical compositions for the treatment of various disorders (p. 110). However the specification does not disclose any diseases or conditions known to be associated with the encoded protein. Further research would be

required to identify a disease in which the encoded protein is involved. See *Brenner v. Manson*, noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. Further research would be required to determine how and if PRO 1291 is involved in any disease.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The specification fails to assert any activity for the polypeptide. Applicants have not asserted that PRO 1291 is a member of any protein family nor have Applicants asserted that PRO 1291 is homologous to any known proteins. Although PRO 1291 is homologous to an ovarian carcinoma polypeptide (see U.S. Patent No. 6,468,546), this is not sufficient to endow the polypeptide with a well-established utility. The '546 patent teaches that the ovarian carcinoma polypeptide is a marker for ovarian cancer. However, this is not a well-established utility because it is neither well known nor readily apparent from Applicant's disclosure of a single sequence. One of skill in the art would not recognize that an anti-PRO 1291 antibody could be used for this purpose.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is drawn to an antibody that specifically binds to a polypeptide comprising SEQ ID NO: 60 (PRO 1291). The term "specifically binds" is a relative term which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one skilled in the art would not be reasonably apprised of the scope of the invention. It is

unclear what amount of binding would be considered to be "specific". One skilled in the art would not know what the metes and bounds of specific binding are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 4-6 are rejected under 35. U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,468,546. Claims 1, 2, and 4-6 are drawn to monoclonal antibodies, fragments of antibodies, or labeled antibodies that bind to a polypeptide consisting of SEQ ID NO: 60. The '546 patent teaches SEQ ID NOS: 392 and 393, which are 100% identical to SEQ ID NO: 60 (see attached alignments). The '546 patent teaches antibodies and fragments of antibodies that bind to a polypeptide comprising SEQ ID NO: 392 or 393. The '546 patent teaches monoclonal antibodies (see "Binding Agents" section). The '546 patent also teaches the use of labeled binding agents for detecting a polypeptide comprising SEQ ID NO: 392 or 393 (see "Methods for Detecting Cancer" section). Thus, claims 1, 2, and 4-6 are anticipated by the '546 patent.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen (U.S. Patent Application Publication 2002/0168762). Claims 1, 2, and 4-6 are as stated above. Claim 3 is drawn to anti-PRO 1291 humanized antibodies. Chen teaches a polypeptide (SEQ ID NO: 5, B7-H4) which is 100% identical to SEQ ID NO: 60. Chen teaches monoclonal and humanized anti-B7-H4 antibodies (see "B7-H3 and B7-H4 Antibodies" section). Chen teaches anti-B7-H4 antibody fragments. Thus, claims 1-6 are anticipated by Chen.

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Ople *et al.* (U.S. Patent Application Publication 2002/0051990). Claims 6 are as stated above. Ople *et al.* teach a polypeptide sequence (see Figures 7A and 7B and attached alignments) which is 100% identical to SEQ ID NO: 60. Ople *et al.* also teach monoclonal antibodies, humanized antibodies, labeled antibodies, and antibody fragments that bind to gene B (Oreo, seen in Figure 7B, see paragraph [0063]). Thus, claims 1-6 are anticipated by Ople *et al.*

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Fox *et al.* (U.S. Patent Application Publication 2002/0165347). Claims 1-6 are as stated above. Fox *et al.* teach a polypeptide (see SEQ ID NO: 2 and Figure 1A and 1B) which is 100% identical to SEQ ID NO: 60. Fox *et al.* teach monoclonal antibodies, fragments of antibodies, humanized antibodies, and labeled antibodies that bind to a polypeptide comprising SEQ ID NO: 2 (see "Selective Binding Agents" section). Thus, claims 1-6 are anticipated by Fox *et al.*

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBK
6/10/04